

Guidance Document: Testing for Detection and Differentiation of Influenza A Virus Subtypes Using Multiplex Nucleic Acid Assays.” See § 866.1(e) for the availability of these guidance documents.

[74 FR 52138, Oct. 9, 2009]

Subpart E—Immunology Laboratory Equipment and Reagents

§ 866.4070 RNA Preanalytical Systems.

(a) *Identification.* RNA Preanalytical Systems are devices intended to collect, store, and transport patient specimens, and stabilize intracellular RNA from the specimens, for subsequent isolation and purification of the intracellular RNA for RT-PCR used in *in vitro* molecular diagnostic testing.

(b) *Classification.* Class II (special controls). The special control is FDA’s guidance document entitled “Class II Special Controls Guidance Document: RNA Preanalytical Systems (RNA Collection, Stabilization and Purification System for RT-PCR Used in Molecular Diagnostic Testing).” See § 866.1(e) for the availability of this guidance document.

[70 FR 49863, Aug. 25, 2005]

§ 866.4100 Complement reagent.

(a) *Identification.* A complement reagent is a device that consists of complement, a naturally occurring serum protein from any warm-blooded animal such as guinea pigs, that may be included as a component part of serological test kits used in the diagnosis of disease.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9.

[47 FR 50823, Nov. 9, 2001, as amended at 66 FR 38792, July 25, 2001]

§ 866.4500 Immunelectrophoresis equipment.

(a) *Identification.* Immunelectrophoresis equipment for clinical use with its electrical power supply is a device used for separating protein molecules.

Immunelectrophoresis is a procedure in which a complex protein mixture is placed in an agar gel and the various proteins are separated on the basis of their relative mobilities under the influence of an electric current. The separated proteins are then permitted to diffuse through the agar toward a multispecific antiserum, allowing precipitation and visualization of the separate complexes.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9.

[47 FR 50823, Nov. 9, 1982, as amended at 54 FR 25047, June 12, 1989; 66 FR 38792, July 25, 2001]

§ 866.4520 Immunofluorometer equipment.

(a) *Identification.* Immunofluorometer equipment for clinical use with its electrical power supply is a device used to measure the fluorescence of fluorochrome-labeled antigen-antibody complexes. The concentration of these complexes may be measured by means of reflected light. A beam of light is passed through a solution in which a fluorochrome has been selectively attached to serum protein antibody molecules in suspension. The amount of light emitted by the fluorochrome label is detected by a photodetector, which converts light energy into electrical energy. The amount of electrical energy registers on a readout system such as a digital voltmeter or a recording chart. This electrical readout is called the fluorescence value and is used to measure the concentration of antigen-antibody complexes.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9.

[47 FR 50823, Nov. 9, 1982, as amended at 54 FR 25047, June 12, 1989; 66 FR 38792, July 25, 2001]

§ 866.4540 Immunonephelometer equipment.

(a) *Identification.* Immunonephelometer equipment for clinical use with its electrical power supply is a device that measures light